ALK provides update on regulatory process for the house dust mite allergy tablet in China

ALK (ALKB:DC / OMX: ALK B / AKBLF) today announced that it has decided to withdraw the Biologic License Application ('BLA') for its house dust mite ('HDM') sublingual allergy immunotherapy tablet in China. ALK will continue to work with the authorities to obtain regulatory approval of the HDM tablet in China, which may involve establishing additional clinical data in Chinese patients.

The delay in the regulatory approval process does not impact ALK's financial guidance for 2024, or its ability to reach a 25% EBIT-margin in 2025. Moreover, it does not impact ALK's ability to meet its previously communicated long-term financial growth ambitions.

The BLA for the treatment of persistent moderate-to-severe HDM allergic rhinitis in patients aged 12–65 was accepted for review by the Chinese authorities in February 2023. In March 2022, prior to the submission, the authorities issued a clinical trial waiver, allowing ALK to file for approval based on clinical data obtained from patients outside of China, without the need to complete the clinical trial with Chinese subjects, which had been paused in 2020 due to COVID.

Commenting on the decision to withdraw the application, ALK's Executive Vice President of Research & Development, Henriette Mersebach, says: "*We remain committed to bringing innovative treatments to the millions of Chinese people with allergy and their doctors asking for better allergy care. We will work with the authorities in order to resubmit an updated registration application as soon as possible. The continued roll-out of the tablet in certain parts of China's Medical Pilot Zones is not impacted and continues according to plan. This allows selected prescribers and patients access to care and to gain experience with the treatment.*"

ALK's commercial plans and activities in China will be adapted to a new launch timeline (previously planned for 2025), which will be determined following further dialogue with the authorities. ALK's current business in China is focused on the injectable SCIT product ALUTARD SQ® which has seen sales growing by 30% p.a. on average in recent years (CAGR 2020-23).

ALK's HDM tablet is approved in 43 countries across Europe, North America, Middle-East and the Asia Pacific region for the treatment of persistent moderate-to-severe HDM induced allergic rhinitis and in some countries also for the treatment of HDM induced allergic asthma.

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About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,900 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.